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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,843	10/04/2001	Ronald C. Rubenstein	CHOP.0107	1601

110 7590 10/21/2003

DANN, DORFMAN, HERRELL & SKILLMAN  
1601 MARKET STREET  
SUITE 2400  
PHILADELPHIA, PA 19103-2307

EXAMINER
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WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/21/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/970,843

Applicant(s)

RUBENSTEIN ET AL.

Examiner

Shengjun Wang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 August 2003.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Receipt of applicants' amendments and remarks submitted august 7, 2003 is acknowledged.

#### ***Claim Rejections 35 U.S.C. 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for butyrate or its derivatives as the first compound, and flavone and isoflavone as the second compound, does not reasonably provide enablement for "compound to enhance the trafficking of the mutant CFTR polypeptide to the surface of an epithelial cell" and "compound to increase the chloride ion transport activity of mutant CFTR polypeptide at the surface of the cell" for reasons set forth in the prior office action.

#### ***Claim Rejections 35 U.S.C. 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. (US 5,972,995) and Fischer et al. (US 6,329,422) for reasons set forth in the prior office action.

*Response to the Arguments*

Applicants' amendments and remarks submitted August 7, 2003 have been fully considered, but are not persuasive for reasons discussed below.

Applicants assert that the claimed invention is enabled and states that the functional language recited in the claim is not the point of novelty of the instant claims. The rebuttal arguments are not persuasive. Applicants' interpretation of "point of novelty" is improper. The functional language herein represent one of the critical limitations in the claims (the therapeutical agents in a therapeutical method). Take the claimed subject matter as whole, the limitation about the therapeutical agents is one of essential part of subject matter. As stated in the prior office action, applicants fail to provide sufficient guidance, direction, or working examples as to how to obtain, identify or make the compounds herein. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The skilled artisan would not know what compounds would possess such functionalities. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed of physiological activity. The instant claims read on all compounds having the functions defined herein, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention, absent undue experimentation. Such functional language "does little more than outline goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate."

The arguments that the compounds are well known in the art, and method of screening such compounds are known in the art are not persuasive. As stated above, the claims are enabled for the known compounds herein disclosed, but not enabled in the scope commensurate with the

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claims. A screen method is not a sufficient for enabling compounds. One of ordinary skill in the art need to know how to make the compounds, which are not disclosed by applicants.

Applicants argue that the instant inventions are not obvious over the cited prior art because the prior art does not teach the limitation “chronic intermittent treatment schedule.” The examiner disagrees. Particularly, such limitation is not sufficient to make the claimed invention patentably distinct from the cited prior art. “Chronic intermittent treatment schedule” is defined herein as “the prescribed times and method by which a compound or combination of compounds can be given to maximize benefit and avoid tolerance” (page 17, the last paragraph in the specification). The limitation is nothing but an optimization of result effective parameters, e.g., dosage, timing. Such optimization is considered within the skill of artisan. See prior office action.

Regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant’s burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). The examiner fails to see any data that provide clear and convincing evidence for unexpected results which commensurate in scope with claimed invention.

Nothing unobvious is seen in the claimed invention.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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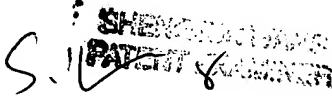
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner

  
Shengjun Wang

August 16, 2003